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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO CONFIRMATION NO. 09/743,107 08/21/2001 Lars A. Hanson 003300-723 5780 05/07/2002 BURNS DOANE SWECKER & MATHIS L L P EXAMINER POST OFFICE BOX 1404 KAM, CHIH MIN ALEXANDRIA, VA 22313-1404 ART UNIT PAPER NUMBER 1653 DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No. Applicant(s) HANSON ET AL 09/743 107 Office Action Summary Examiner Art Unit Chih-Min Kam 1653 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Statue 1) Responsive to communication(s) filed on ____. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-32 and 43-53 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-32 and 43-53 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) The translation of the foreign language provisional application has been received.

U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)

Attachment(s)

6) Other:

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

4) Interview Summary (PTO-413) Paper No(s). _____
5) Notice of Informal Patent Application (PTO-152)

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Claims 1-32 and 43-53, drawn to a peptide based on the sequence of amino acids 12-40 of human lactoferrin from the N-terminal end, a modified version thereof, or a fragment thereof; a medicinal product comprising a peptide of claim 1; and a method for treating or preventing infection or inflammation by administering a peptide of SEO ID NO:1-7, 31-38 or 46-99, classified in class 514, subclasses 2 and 12.

Upon review of the claims, there are at least one hundred distinct peptides claimed, therefore, in order to provide a search of the claimed peptides, Applicants must choose a single peptide having a sequence identifier from claims 1-32 and 43-53 for search. Each peptide is considered, absent factual data to the contrary, a distinct peptide. This is not a species election. The elected invention does not include homologs and analogs of the sequence.

Additionally, if there is a specific core sequence that unifies several sequences, applicants should point out this core sequence and the sequences comprising these core sequences with sequence identifiers. The examiner will then reconsider this restriction requirement to include the additional sequences for examination. However, only the core sequence pointed out by

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applicants will be searched; any art that anticipates the core sequence will be considered as anticipatory or obvious. Upon election, all other sequences will be withdrawn from further consideration by the examiner as directed to non-elected inventions.

Regarding the disease of infection or inflammation, applicants is required to select one disease from urinary tract infection, colitis or candida infection on a mucosal membrane cited in claims 44-46. Each disease is considered patentably distinct because the diagnosis of each disease state is different, each disease can be treated with a different drug and has different outcome for the treatment.

The claims are directed to different inventions which are not linked to form a single general concept. The claims containing different sequences do not have in common the same or corresponding technical features. In particular, each peptide sequence is directed to a distinct chemical entity, which produces different effects. Accordingly, the claims are not so linked by a special technical feature which is demonstrated to be found in the prior art of JP 0714596 within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a petition under 37 CFR

1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call was made to Benton Duffett, Jr. on May 3, 2002 to request an oral

election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The

examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-0294 for regular

communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. Cuk

Patent Examiner

May 3, 2002

Chi hard S. F. LOW

CHRISTOPHER S. F. LOW

SUPERVISORY PATENT EXAMINER